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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,235	06/22/2001	Joan P. Blonder	42830-00234	8106
25231	7590	01/28/2004		
MARSH, FISCHMANN & BREYFOGLE LLP 3151 SOUTH VAUGHN WAY SUITE 411 AURORA, CO 80014				
			EXAMINER	
			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/888,235

Applicant(s)

BLONDER ET AL.

Examiner

Bao.Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,9-31 and 33-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,9-31 and 33-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78:  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1, 4-7, 9-31 and 33-44 are pending.

#### **RCE**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/2003 has been entered. The Office Action of RCE follows:

#### ***Response to Amendment***

This is a response to the amendment, paper No. 15, filed 10/28/03. Claims 1, 9 and 31 have been amended. Claims 2-3, 8, 32 and 45-147 have been canceled. Claims 1, 4-7, 9-31 and 33-44 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 4-7, 9-31 and 33-44 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian et al. (b) (US Patent No. 6,416,947B), Viegas et al. (a: US Patent No. 5,071,644 and B: 5,593,683), Illum et al (a: Pharmaceutical Research, 1994, Vol. 11, No. 1186-1189), Cox (Vaccine 1997, Vol. 15, pp. 248-256) and Horner et al. (Cellular Immunology 1998, Vol. 190, pp. 77-82) or over Ron et al. (WO 98/06438), Illum et al. (a: Pharmaceutical Research, 1994, Vol. 11, No. 1186-1189), Cox et al. (Vaccine 1997, Vol. 15, pp. 248-256), Horner et al. (CELLULAR IMMUNOLOGY 1998, Vol. 190, pp. 77-82) on the same ground as stated in the previous Office Action.

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3. Applicants asserted that as discussed in the prior-filed Response To Office Action (filed April 28, 2003 by certificate of mailing procedure), the references of record do not disclose or suggest the specific combination of elements and formulation properties recited in the pending claims. Withdrawal of the rejection based on 35 U.S.C. 103(a), and issuance of a notice of allowance are respectfully requested.

4. Previously, Applicants submitted that Office Action appears to pick and choose claimed elements from a number of references and then, apparently using hindsight with the invention as guide, to find obvious the combination of these elements in the precise manner of the invention. Applicants further emphasized that the nature of the invention of claims 1-44 is not the discovery of new antigens, new polymers, or new adjuvant, but it rather a very specific and narrow combination of components and a formulation properties for an antigen delivery composition. Moreover, Applicants further argued that examiner has made no showing of why one of ordinary skill in the art would select the specific components recited in claims 1-44 and then combine those specific components in the specific and narrow combination of claims 1-44.

5. In the previous Office Action, the examiner stated that the examiner's conclusion of obviousness is not based upon improper hindsight reasoning, it is based on the judgment on the knowledge which was within the level of ordinary skill at the time the claimed invention was made, which does not include knowledge gleaned only from the applicant's disclosure.

6. For example, the function of each component, such as property of reverse thermal viscosity of polyalkylene block copolymer is known in the art as disclosed by Balasubramanian et al. (b) (US Patent No. 6,416,947B), Viegas et al. (a: US Patent No. 5,071,644 and B: 5,593,683). The fact of CpG motif, the cytokine or chitosan being able to produce an enhanced immune response when they are co-administered with an antigen are all well known in the art as disclosed by Illum et al (a: Pharmaceutical Research, 1994, Vol. 11, No. 1186-1189), Cox (Vaccine 1997, Vol. 15, pp. 248-256) and Horner et al. (Cellular Immunology 1998, Vol. 190, pp. 77-82) or over Ron et al. (WO 98/06438), Illum et al. (a: Pharmaceutical Research, 1994, Vol. 11, No. 1186-1189), Cox et al. (Vaccine 1997, Vol. 15, pp. 248-256), Horner et al. (CELLULAR IMMUNOLOGY 1998, Vol. 190, pp. 77-82). Therefore, it would have been obvious for any person with ordinary skill in the art to be motivated to make an immunogenic

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composition that producing an enhanced immune response by just COMBINING EQUIVALENTS KNOWN MATERIALS IN THE ART FOR THE SAME PURPOSE.

7. Applicants' attentions are directed to the MPEP 2144.06 regarding to **"Art Recognized Equivalence for the Same Purpose"**, which cites that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850. The board held that it would have been prima facie obvious, within the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive...". Because Applicants have not shown that he claimed invention is an unexpected result, the rejection is still maintained as a prima facie obvious absence of unexpected result.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

January 22, 2004

 1/24/04

EXAMINER  
JAMES C. HOUSEL  
1/24/04